

DATE OUT: 27/JAN/2003

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]
DP BARCODE #: D285611 EPA RECEIVED DATE: 04/SEP/2002 FILE SYMBOL/REG # 74843-E
PRODUCT NAME: Buzz Off Insect Shield Apparel, 0.52% Permethrin MRIDs: 457519-01 & 457595-01
COMPANY NAME: Buzz Off Insect Shield, LLC NON-Food Use [X] ACTION CODE: 170**

FROM: Sami Malak, Chemist
Technical Review Branch/RD (7505C)

TO: 03 Arnold Layne/Susan Stanton
Insecticide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 04/SEP/2002, ChemReg International an agent for the applicant requested a FIFRA sec.3(c)(3)(B)(i)(I) "me-too" registration of subject product claiming its similarity to currently registered products containing permethrin. In support of this action, the applicant included product chemistry data, a proposed CSF dated 30/AUG/2002, a proposed label EPA received 04/SEP/2002, Certificate With Respect to Citation of Data, and Data Matrix. this application.

FINDINGS:

- 1a. The subject product is produced by an integrated formulation system, meaning that one of two active ingredients in the product is not registered. The product contains 0.52% permethrin. The second source is registered, Reg. No. [REDACTED]
- 1b. The subject product, an insecticide, is intended to be incorporated into garments to serve as human shield in repelling insects. Repellant remains effective for 35 washings but lose its effectiveness if dry cleaned.
- 2a. A FIFRA sec.3(c)(3)(B)(i)(I) "me-too" registration for subject product can not be processed because (1) no citation for a registered product was made in box 6 of EPA Form 8570-1 or in the cover letter dated 04/SEP/2002; and (2) the product was formulated using a non-registered source, and a claim of a repack was made for a second registered source, Reg. No. [REDACTED]
- 2b. Because of Finding 2(a) above, this application was reviewed as per the regulation of FIFRA sec. 3(c)(5) unconditional or sec. 3(c)(7) conditional registration.
- 3a. The applicant should be advised to remove from the CSF the non-registered [REDACTED] [REDACTED]. Alternatively, submit the full product chemistry data requirements for that source whether or not a registration is sought. If a registration is not requested for [REDACTED] the applicant will need to list all carryover impurities in future submissions of all formulated products.
- 3b. The applicant should be advised to remove from the CSF the "repack" claim using Reg. [REDACTED] and use that source at the proper dose in the garments to achieve the label claim nominal concentration of 0.52% permethrin. Since its purity was found to be 40% (REFs), the percentage by weight needed was calculated by this reviewer at 1.3%. The nominal concentration of 0.52% can be indicated between parenthesis below the percentage by weight and the corresponding upper and lower certified limits can be indicated in columns 14(a) & 14(b) of the CSF, calculated by this reviewer at 0.572 & 0.468%, respectively..

PRODUCT/REGISTRATION SOURCE INFORMATION IS NOT INCLUDED

- 4a. The waiver request for product chemistry data requirements of OPPTS Test Guidelines, Group "B" pertaining to the physical/chemical properties may be justified since almost all the properties of the technical source will apply because it will be incorporated into garments, i.e. no intentionally added inert ingredients. This reviewer, however, is reluctant to accept waiver of all the physical/chemical properties because of a concern over flammability and corrosion to the garments, as well as storage stability as a measure for product's stability, hence effectiveness, for a period of one year.
- 4b. Because Finding 4(a) above, the applicant should be advised to submit three product chemistry data requirements for subject product pertaining to flammability (GRN 830.6315), storage stability (GRN 830.7317), and corrosion characteristics (GRN 830.6320). The test substance would be pieces of garments treated with permethrin.
5. The submitted/referenced product chemistry data is adequate and support a FIFRA sec. 3(c)(7) conditional registration of subject product.
6. Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with the registration of the registered technical source, permethrin, [REDACTED]
- 7a. The label claim nominal concentrations of 0.52 permethrin is consistent with that on the CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement is in compliance with the regulations of 40CFR§156.10.
- 7b. After resolving Finding 4(b) above regarding flammability, a label statement under the physical or chemical hazards may be needed.
- 7c. The balance of 100% on the label should be indicated as such: "Other Ingredients composed of garments."
8. The submitted product's CSF dated 30/AUG/2002, is unacceptable until Findings 3(a), 3(b) & 4(b) above are resolved. Further, box "A" of the CSF should be checked to indicate it is a basic formulation.

CONCLUSIONS:

TRB recommends for a conditional registration for subject product as per the regulations of FIFRA sec. 3(c)(7) pending resolution of Findings 3(a), 3(b), 4(b), 7(b) & 7(c) above. Product label is conditionally acceptable [Finding 7(a)]. The proposed CSF dated 30/AUG/2002 is unacceptable (Finding 8) above.

NOTE TO PM:

Please note Finding 2(a) above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 30/AUG/2002 was included with this submission claiming confidentiality of some of the submitted data on the basis of its falling within the scope of FIFRA§ 10(d)(1)(A), (B), or (C). Review of CBI data was removed to Confidential Appendix A.

2. A GLP statement dated 30/AUG/2002 was included with this submission to the effect that the submitted studies do not fall within the scope of the GLP requirements of 40CFR§160.

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

The subject product contains two active ingredients, permethrin, one of which is not registered and the second was claimed to have been used as a 100% repack. The product contains 0.52% permethrin to be incorporated into garments.

830-1600 Description of Materials Used to Produce the Product:
Refer to Confidential appendix A.

830-1650 Description of Formulation Process:
Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:
Refer to Confidential appendix A.

830-1700 Preliminary Analysis:
Refer to Confidential appendix A.

830-1750 Certified Limits:
Refer to Confidential appendix A.

830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with the registration of the registered technical source, permethrin, Reg. No. [REDACTED]

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

Confidential Appendix A830-1600 Description of Materials Used to Produce the Product:

permethrin and garments.

830-1650 Description of Formulation Process:830-1670 Discussion of Formation of Impurities:

The applicant reported no impurities $\geq 0.1\%$ by weight were known to be formed during formulation and storage of the product. There was no chemical reaction in the process.

830-1700 Preliminary Analysis:

Will be required if registration of one of two active ingredients is not imminent.

830-1750 Certified Limits:

The applicant reported the same certified limits as those in product's CSF, a basic formulation dated 30/AUG/2002.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

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